REMARKS

In the Non-Final Office Action mailed September 17, 2008, claims 39-53, 57, 60, 74-76 and 87-94 were pending. Claims 39-53, 57, 60, 74-76 and 87-94 currently stand rejected. New independent claim 95 is added. In view of the following remarks, Applicant respectfully requests reconsideration and allowance of the present application, including claims 39-53, 57, 60, 74-76 and 87-95.

Applicant acknowledges and thanks the Examiner for the indication in the outstanding Action that Applicant's arguments of the previously-asserted rejection of claims 39, 49, 57, 74, 76 and 88 were found persuasive and that this rejection has been withdrawn, together with all further rejections of claims under 35 U.S.C. §103(a).

Of the claims rejected in the outstanding Action, only claim 39 is an independent claim. The outstanding Action asserts two new rejections of claim 39, as follows: (1) claim 39 is rejected under 35 U.S.C. §112, first paragraph, on the grounds that the specification, while being enabling for a solid particulate material selected from the group zinc oxide, talc, calamine or kaolin, does not reasonably provide enablement for all solid particulate materials; and (2) claim 39 is rejected under 35 U.S.C. §103 as being unpatentable over Paul et al. (US 6,217,890) in view of Goldberg et al. (US 5,176,903), and further in view of Heilig (US 3,079,299). Each of these rejections is addressed below.

Response to Rejection Under 35 U.S.C. §103

First with regard to the rejection of claim 39 under 35 U.S.C. §103, Applicant submits that this rejection is improper because the primary reference cited in the Action, Pau et al. 1, is not prior art to the present application. The present application is a continuation of prior U.S. Patent Application No. 09/364,133, filed July 30, 1999, now U.S. Patent No. 6,627,178. The Paul et al. patent issued from U.S. Patent Application No. 09/379,431, filed August 23, 1999. Because the filing date of Paul et al. is after the effective filing date of the present application, Applicant submits that Paul et al. does not qualify as prior art to the claims of the present application under 35 U.S.C. §102(e) or any other provision of the Patent Statute. Applicant acknowledges that the Paul et al. patent is a continuation-in-part of several prior applications and includes a claim of priority to a prior provisional patent application; however, applicant submits

that subject matter of Paul et al. relied upon in the outstanding Action does not find support in the prior nonprovisional patent applications to which Paul et al. claims priority. Moreover, provisional patent application No. 60/141,788 is not available in the on-line records of the U.S. Patent Office, and Applicant therefore has not had an opportunity to consider its content. Nevertheless, even if the subject matter relied upon in the outstanding Office Action is present in the '788 provisional, it appears that the filing date of the '788 provisional is June 30, 1999, which is only thirty (30) days before the effective filing date of the present application. Thus, even if a rejection is made based upon subject matter in the '788 provisional, Applicant expressly reserves the right to overcome such a rejection by swearing behind the filing date of the '788 provisional under 37 C.F.R. 1.131.

In addition, while it is not believed necessary because the Paul reference is not prior art, Applicant reserves the right to present arguments traversing the rejection of claim 39 under 35 U.S.C. §103 over the asserted combination of Paul et al., Goldberg et al. and Heilig on the grounds that, even if Paul et al. were to qualify as prior art, the Action still fails to establish a *prima facie* case of obviousness of the subject matter of claim 39 over the cited references.

Claims 40-53, 57, 60, 74-76 and 87-94 depend, either directly or indirectly, from independent claim 39, and are believed to define patentable subject matter over the cited references for at least the same reasons that the subject matter of independent claim 39 is patentable, and for other reasons.

Response to Rejection Under 35 U.S.C. §112, first paragraph

With regard to the rejection of claim 39 under 35 U.S.C. §112, first paragraph, the Action asserts that, upon application of the *Wands* factors (*In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404), "the applicant is enabled for treating diaper rash with a solid particulate material selected from the group of zinc oxide, talc, calamine or kaolin, but not for any solid particulate material." (emphasis in original). Applicant traverses this rejection and submits that the subject matter recited in claim 39 satisfies the enablement requirement of 35 U.S.C. §112, first paragraph.

Analysis of whether a claim satisfies the enablement requirement of 35 U.S.C. §112, first paragraph, requires a determination of whether a person of ordinary skill in the art can make and

use the claimed invention without undue experimentation. As stated in Section 2164 of the Manual of Patent Examining Procedure ("MPEP"), "The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph, that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent." Applicant submits that the specification fully and clearly describes how to make and use the invention set forth in claim 39.

In the outstanding Action, the enablement analysis focuses upon the solid particulate material of the diaper rash treatment composition recited in claim 39. Applicant submits, as described more fully below, that this focus is improper. Upon considering the subject matter of claim 39 as a whole, the proper analysis with regard to the diaper rash treatment composition recited therein includes a 2-part inquiry regarding whether the specification includes sufficient descriptions that a person of ordinary skill in the art, upon reading the specification, would be able to:

(A) make a composition comprising "(1) a fluid base material comprising a member selected from the group consisting of mineral oil, silicone oil, an organic solvent, plant-based oil, water and mixtures thereof, and (2) a solid particulate material" wherein "the composition is a fluid composition having a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser and sufficiently high that the coating does not run off of the skin treatment area," and

(B) use the composition by "passing the composition through the mechanism to atomize the composition and to propel the atomized composition toward the skin treatment area to provide a moisture barrier over the skin treatment area."

There is no limitation in claim 39 requiring that the solid particulate material have a therapeutic effect, produce any particular result or effect on the patient's skin, or have any particular function on the skin treatment area, and the only function of the diaper rash treatment composition as a whole recited in claim 39 is to "provide a moisture barrier over the skin treatment area."

The enablement analysis in the outstanding Action, however, erroneously focuses on a subjective consideration of whether the solid particulate material in the diaper rash treatment composition recited in claim 39 would be "useful to treat diaper rash" according to some unstated and undefined subjective standard. The discussion of various *Wands* factors in the Action is misplaced because it erroneously focuses on an unclaimed functionality of the solid

particulate material. When considering the first *Wands* factor identified in the Action, the nature of the invention, the overall analysis set forth in the outstanding Action mischaracterizes the nature of the invention recited in claim 39. Specifically, the Action appears to imply that the treatment of diaper rash in accordance with the subject matter of claim 39 involves only the delivery of a solid particulate material to a skin treatment area, and appears to imply that the solid particulate material recited in the claim is required to have a therapeutic effect. In this regard, the Action states the following: "Claim 39 embraces treating diaper rash with any solid particulate material." (Action page 4, second full paragraph) (emphasis in original); "The predictability treating diaper rash with any solid particulate material is relatively low. Therefore, to one skilled in the art, treating diaper rash with any solid particulate material is highly unpredictable." (Action, page 4, last paragraph) (emphasis in original); and "The specification as filed does not speak on or show any working examples any studies performed that demonstrate that any solid particulate material can treat diaper rash." (Action, page 5, middle paragraph) (emphasis in original).

These implications, however, mischaracterize the nature of the invention recited in claim 39, and ignore the full content of claim 39, which recites a method for treating diaper rash that includes additional features and, in particular, involves the delivery of a "diaper rash treatment composition," of which only one component is a "solid particulate material." The diaper rash treatment composition recited in claim 39 also includes a "fluid base material comprising a member selected from the group consisting of mineral oil, silicone oil, an organic solvent, plant-based oil, water and mixtures thereof."

In addition, the Action states at page 5 that, "Melloh et al. (US 4,307,089) teaches that the solid particulate, sodium pyrithione irritates skin in 40 and 48% solutions. Thus, all solid particulates are not useful to treat diaper rash because they can irritate the skin." The question of whether "all solid particulates are...useful to treat diaper rash," i.e., whether a given solid particulate material has some undefined subjective "functionality," is not pertinent to the question of whether the specification sufficiently describes the subject matter that is recited in claim 39 so that a person of ordinary skill in the art would understand how to make and how to use the claimed subject matter. Claim 39 does not recite a limitation regarding a tolerable level of skin irritation for the solid particulate material, and so it is improper to assert that the subject matter fails to

satisfy the enablement requirement of Section 112, first paragraph, on the grounds that the diaper rash treatment composition recited in the claim includes a solid particulate material that could be subjectively considered to cause too much skin irritation. In other words, whether a given solid particulate material causes skin irritation, or has any therapeutic effect, is not pertinent to the question of whether a person of ordinary skill in the art can make the diaper rash treatment composition recited in claim 39 and apply the composition to a skin treatment area as recited in claim 39. As an ancillary matter, Applicant would also note that sodium pyrithione is described in the Melloh et al. patent as being a skin irritant when in a highly concentrated solution, but this compound is not a solid particulate material when it is in solution form, and thus its presence in solution form would not satisfy the recitation of "a solid particulate material" in claim 39.

In view of the above, Applicant submits that the specification of the present application clearly enables a person of ordinary skill in the art to practice the invention recited in claim 39 without undue experimentation. While the solid particulate material can be of a type that is generally accepted as having a protective or otherwise beneficial effect on skin or on diaper rash, such as, for example, zinc oxide, talc, calamine or kaolin, the specification of the present application makes no representation requiring that the solid particulate material must have a protective or therapeutic effect or any other beneficial effect on skin or on diaper rash in order to be included in a diaper rash treatment composition as described therein, and claim 39 includes no limitation requiring such. The solid particulate material need not have such an effect. For example, a solid particulate material can be included in a diaper rash treatment composition solely to affect the physical properties of the diaper rash treatment composition, such as, for example, its viscosity, which will have an effect on the spraying and coating features of the composition. As stated in the specification in connection with one embodiment that includes zinc oxide as the solid particulate material:

> The ratio of zinc oxide to fluid base material in the composition is preferably selected such that the composition has a suitable viscosity at a given temperature as described above. It is readily understood that the ratio selected is dependent upon the desired viscosity for a given system. For example, different delivery systems may function optimally when used to deliver compositions having different overall viscosities. Further, the preferred ratio also depends upon the viscosity of the fluid base material selected for use and upon the particulate size distribution of the zinc oxide. These and other factors may be readily determined

> and considered by a person of ordinary skill in the art, without undue experimentation, to make an inventive composition having a suitable viscosity.

(published application, paragraph [0044]).

With the above in mind, it is well within the purview of a person of ordinary skill in the art to select and include a solid particulate material in a diaper rash treatment composition as recited in claim 39 from a wide variety of different possibilities, and a person of ordinary skill in the art would have clearly understood that the descriptions in the specification encompass more than the few materials that are described in the specification as examples or as preferred embodiments. Contrary to what is stated in the Action, the effect of a solid particulate material on the viscosity, the sprayability and the barrier functionality of a composition as recited in claim 39 is predictable in view of the descriptions in the present specification, and could be determined without undue experimentation. The ability of the composition to be passed through the mechanism to atomize the composition and to propel the atomized composition toward the skin treatment area would depend upon, for example, the size fraction of the particles, the type of fluid base material selected and the ratio of particulate solid material to fluid base material, as discussed above and described in the specification.

For all of the above reasons, Applicant respectfully submits that the rejection of claim 39 under 35 U.S.C. §112, first paragraph, is improper, and respectfully request that it be withdrawn.

Finally, Applicant would draw the Examiner's attention to new claim 95. New claim 95 is the same as claim 39 except that new claim 95 recites that the solid particulate material comprises "a member selected from the group consisting of zinc oxide, talc, calamine and kaolin." It is believed that this claim is also in condition for allowance.

Closing

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, including claims 39-53, 57, 60, 74-76 and 87-95, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: _____

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